



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

021005 03/27/00 FAN

0225.1016-00

021005 HME2/0322
HAMILTON BROOK SMITH AND REYNOLDS, P.C.
TWO MILITIA DR
LEXINGTON MA 02421-4799

EXAMINER

WILDER, C
ART UNIT

PAPER NUMBER

1655
DATE MAILED:

03/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/536,841

Applicant(s)
FAN et al.

Examiner
CB Wilder

Group Art Unit
1655



☒ Responsive to communication(s) filed on Feb 23, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-40 is/are pending in the application.

Of the above, claim(s) 3-19 and 26-40 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, and 20-25 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Application/Control Number: 09/536,841

Art Unit: 1655

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 1, 2, 20-25 in Paper No. 7 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)) and is therefore made FINAL.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged for provisional applications 60/126,473 filed March 26, 1999 and 60/140,359, filed June 23, 1999.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

4. Claims 1-2, 20, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Art Unit: 1655

(a) Claims 1 and 2 are indefinite the phrase "for example (e.g.)" because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

(b) Claims 20 and 21 are indefinite and confusing at "wherein the extension primer terminates one nucleotide 5' to the polymorphic locus" because the primer set is not drawn to a method and it is unclear how the claimed structural features of the primer set "terminate" one nucleotide 5' to the polymorphic locus. Additionally, it cannot be determined if the claimed "termination" of the extension primer is 5' the terminal end of the primer itself or 5' the target sequence comprising the polymorphic locus".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Eyal and Navot (2,170,950 September 1997). Regarding claims 20 and 21, Eyal and Navot teach a primer set and kit comprising the primer set wherein the primer set comprise a pair of primers which when in the presence of a DNA polymerase amplify a region of DNA and an extension primer which comprises a 3' portion which is complementary to a portion of the region of DNA and a 5' portion which is not complementary to the region of DNA wherein the extension primer terminates one nucleotide 5' to

Art Unit: 1655

the polymorphic locus (page 6, lines 6-11, page 25, lines 24-28 and Example 6). Therefore the claimed invention of claims 20 and 21 are anticipated by the reference of Eyal and Navot.

7. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soderlund et al. (WO 91/13075, September 5, 1991). Regarding claim 20-21, Soderlund et al. teach a set of primers for determining specific nucleotide variations in a sample comprising a pair of primers which when in the presence of a DNA polymerase amplify a region of double stranded DNA (page 10, lines 15-25, Example 1, page 21, lines 1-14 and Abstract), wherein the region comprises a polymorphic or variant locus; and an extension primer which comprises a 3' end portion which is complementary to a portion of the region of double stranded DNA and a non-complementary 5' portion (page 9, lines 9-15 and Example 1). Therefore, the claimed invention of claim 20 is anticipated by the reference of Soderlund et al.

Regarding claim 21, Soderlund teaches a single container comprising the sets of primers as described in claim 20 (page 19, lines 5-8).

8. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (WO 93/25563 December 1993). Regarding claim 22 and 23, Wallace et al. teach a set of primers comprising a pair of primers and an extension primer which comprises a 3' portion which complementary to a region of double stranded DNA and a 5' portion which is not complementary to region of DNA but is complementary to different preselected sequences and a solid support comprising a probe which is attached to a solid support wherein the probe is complementary to the 5' end of the extension primer (Page 5, lines 1-20 and page 8, last paragraph. See also Example I).

Art Unit: 1655

Wallace et al. also teach a diagnostic kit comprising the reagents thereof (page 5, lines 19-20).

Therefore the claimed invention is anticipated by the reference of Wallace et al.

Claim Rejections - 35 USC § 102(a)

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.

10. Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Wong et al. (Wong et al. WO 98/15644, April 16, 1998). Regarding claims 1 and 2, Wong et al. teach an oligonucleotide array and kit comprising one or more oligonucleotide tags fixed to a solid support, wherein each oligonucleotide tag comprises a unique known arbitrary nucleotide sequence of sufficient length to hybridize to a locus-specific tagged oligonucleotide, wherein the locus specific tagged oligonucleotide has at its first end nucleotide sequence which hybridizes to, e.g., is complementary to, the arbitrary sequence of the oligonucleotide tag (page 7, lines 15-33, see also Abstract). Wong et al. also teach wherein the locus-specific tagged oligonucleotide has its first 5' end nucleotide sequence which is complementary to the arbitrary sequence of a corresponding oligonucleotide tag on the array and has at its 3' end a template complement region derived from a target sample (page 7, lines 15-27). Therefore the claimed invention of claims 1 and 2 are anticipated by the reference of Wong et al.

Art Unit: 1655

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (WO 93/25563 December 1993) in view of Wong et al. (WO 98/15644). Regarding claim 24 and 25, Wallace et al. teach a set of primers and a solid support comprising a probe which is attached to a solid support wherein the probe is complementary to the 5' end of the extension primer. Wallace et al. also teach a diagnostic kit comprising the reagents thereof. The disclosure of Wallace et al. differs from that of the claimed invention in that Wallace et al. do not teach wherein the solid support is a bead or a microtiter plate. However, solid support for oligonucleotide arrays such as beads and microtiter plate are well known in the prior art for small scale analysis of nucleic acids. For example,

Art Unit: 1655

Wong et al. teach a kit comprising a primer set and a probe array wherein the probe array comprise a two dimensional array of rows and columns on the surface of a solid support such as glass; quartz, silicon, plastic or a membrane (page 18, 29-32). Wong et al. further teach wherein the solid support may include depressions in the support, e.g., microtiter plate, or optionally, the array may consist of individual beads attached to a surface, via magnetic forces if the beads are magnetic or with an adhesive (page 19, lines 20-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a solid support for the oligonucleotide array consisting of a microtiter plate or bead for the benefit of small scale analyses of nucleic acids as well known in the art. Additionally, the solid support for the oligonucleotide array would have been determined by the practitioner based on preference, experimental parameters and desired results.

Conclusion

13. No Claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Art Unit: 1655

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.

Cynthia B. Wilder

Cynthia B. Wilder, Ph.D.

March 20, 2001

W. Gary Jones
W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
3/21/01